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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,008	09/26/2003	Ruitang Deng	3153.00451/PC10172B	1780

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EXAMINER	
GUZO, DAVID	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/673,008	DENG ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/14/05;4/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specifically, non-initialed alterations to the Residence and Post Office Address of inventor Suresh Jeevarathnam have been made to the Declaration.

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Sequences are present in the drawings (Figs. 2-3) which have not been identified by the appropriate SEQ ID NO identifiers. Any response to this Office Action which does not include complete compliance with the Sequence Rules will be considered non-responsive.

Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16, 18 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6,764,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a vaccine composition comprising an immunologically effective amount of a portion of a genome of a FIV strain and a pharmaceutically acceptable carrier. The instant claims are generic to all that is claimed in the '676 patent. That is, claim 6 of the '676 patent falls entirely within the scope of the instant claims, in other words, the instant claims are anticipated by claim 6 of the '676 patent. Specifically, claim 6 recites a FIV vaccine composition comprising a portion of a specific FIV strain molecule (FIV-141 genomic DNA which is mutated by deletion) while the instant claims are generic and recite any portion of any FIV strain (which can

be a sequence comprising a gag encoding sequence, a pol encoding sequence, regulatory encoding sequence, etc.) and a pharmaceutically (veterinarily) acceptable carrier.

Claims 1-16, 18 and 30 are directed to an invention not patentably distinct from claim 6 of commonly assigned 6,764,676. Specifically, the claims are not patentable distinct for the reasons recited in the above obviousness type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US 6,764,676, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claims 1-16, 18 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,667,295. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a vaccine composition comprising an immunologically effective amount of a portion of a genome of a FIV strain and a pharmaceutically acceptable carrier. The specific sequences encoding FIV proteins such as the gag, pol, env, Rev, Vif, etc. proteins which are instantly claimed would have been obvious choices since the claims in the '295 patent are generic as to any FIV protein encoding sequence or combination of sequences and because the specification of the '295 patent specifically recites these sequences as preferred embodiments. The skilled artisan would therefore have been motivated to select these sequences.

It is noted that during the prosecution of the application which issued as 6,667,295 (the parent of the instant application) the inventorship was changed to be identical to the inventorship in the instant application. This change was not reflected on the face of the patent which still lists only Ruitang Deng as the sole inventor.

The examiner notes that the current assignment data for the instant application and the 6,764,676 and 6,667,295 patents is not available in the Office records. It is assumed that they are currently commonly owned. If this is not the case, applicants are required to inform the Office as to the current assignment data.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16, 18 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,764,676.

The instant claims read on vaccine compositions comprising an immunologically effective amount of a polynucleotide molecule(s) selected from a portion of a genome of any FIV strain wherein said polynucleotide(s) can encode one or more FIV structural and/or non-structural FIV proteins. The '676 patent teaches vaccine compositions comprising an immunologically effective amount of a polynucleotide encoding a portion of a FIV-141 strain genome wherein the genome can contain all of the genes normally found in the FIV genome and wherein one or more of the genes can be mutated (i.e. by deletion of a sequence) so as to attenuate the virus (See columns 5-7, Claims 4 and 6). The teachings of the '676 patent therefore anticipate the claimed invention.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-19, 21-26 and 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Luciw et al.

Applicants claim a vaccine composition against FIV comprising an immunologically effective amount of one or more polynucleotide sequences (which can be DNA or RNA) selected from a portion of the FIV genome and comprising sequences encoding at least three (or up to at least 7) different FIV proteins which can be structural, non-structural and regulatory proteins. The vaccine composition can also contain a sequence encoding a cytokine. Applicants also claim a method of preparing said vaccine composition comprising mixing the polynucleotide sequence(s) with a veterinarily acceptable carrier, a method of vaccinating a cat and a kit comprising a container comprising the claimed FIV vaccine.

Luciw et al. (U.S. Patent 6,004,799, issued 12/21/99, filed 3/5/97, see whole document, particularly claims 1-38, columns 3-7) recites a vaccine composition comprising a DNA sequence (which can be in the form of a vector or plasmid) which encodes a portion of the FIV genome and which can contain sequences encoding some or all FIV proteins which can be structural, non-structural or regulatory proteins and are normally expressed by FIV. The vaccine composition can also contain a sequence encoding a cytokine. Luciw et al. also recite a method for preparing said vaccine comprising mixing the DNA and a veterinarily acceptable carrier as well as a method of

vaccinating a cat comprising administering the vaccine composition orally, intradermally, intramuscularly, etc. Luciw et al. also recites storage of the vaccine composition in a container such as a sterile ampoule. Luciw et al. therefore teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6, 8, 15-19, 21-26 and 28-30 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Wardley et al.

Both applicant and Wardley et al. (U.S. Patent 5,833,993, issued 11/10/98, 102(e) date of 10/25/96, see whole document, particularly Claims 1-11, the "Summary of the Invention" on columns 3-4 and columns 7-8) recite FIV vaccine compositions comprising DNA molecules (on the same or different molecules or in viral vectors) encoding FIV gag and env, an adjuvant of choice, a method of preparing said vaccine comprising combining the molecules encoding the FIV gag and env proteins and a veterinarily acceptable carrier and adjuvants), kits comprising said ingredients in a container and a method for vaccinating a cat comprising administering the vaccine composition to the cat in a intramuscular or subcutaneous, etc. manner. It is noted that the FIV gag region encodes three different proteins (MA, NC and CA). Therefore, Wardley et al. teaches the claimed invention.

35 USC 103(a) Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luciw et al. or Wardley et al., either in view of Audonnet et al.

Applicants recite a polynucleotide vaccine composition against FIV wherein the composition is coated onto gold particles.

Luciw et al. and Wardley et al. are cited as in the above 35 USC 102(e) rejection. Luciw et al. and Wardley et al. do not recite use of gold particles, coated with the vaccine composition, as a delivery system for delivering the vaccine to the subject.

Audonnet et al. (U.S. Patent 6,348,196, issued 2/18/02, filed 1/15/99, see whole document particularly column 1) recites the use of gold particles as a delivery system to deliver FIV polynucleotide vaccines to animal subjects.

Luciw et al. and Wardley et al. teach the claimed invention with the exception of the use of gold particles as a delivery system for delivering the vaccine to the animal. The ordinary skilled artisan, seeking to generate a polynucleotide vaccine composition which could be easily delivered to a animal host would have been motivated to coat gold particles with the polynucleotides recited by Luciw et al. or Wardley et al. because Audonnet et al. teaches that gold particles can be used to deliver polynucleotide FIV vaccines to animals. It would have been obvious for the ordinary skilled artisan to do this because of the expected benefit of using a well-known delivery system (coated gold particles) to deliver polynucleotides and polynucleotide FIV vaccines to animals. Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be assumed, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luciw et al. or Wardley et al., either in view of Chavez et al.

Applicants claim an FIV polynucleotide vaccine composition which is in a lyophilized form and is in a first container. Applicants also claim a second container containing a sterile diluent useful to re-hydrate the vaccine composition.

Luciw et al. and Wardley et al. are applied as in the above 35 USC 102(e) rejection. Luciw et al. and Wardley et al. do not recite lyophilization of the vaccine composition.

Chavez et al. (U.S. Patent 6,300,118, issued 10/9/01, filed 6/7/95, see whole document, particularly columns 3-4) recites the standard use of lyophilization to store FIV vaccine preparations and the reconstitution of said vaccines with a sterile diluent.

The ordinary skilled artisan, seeking to generate a kit for vaccinating a cat against FIV, would have been motivated to lyophilize the FIV vaccine compositions taught by Luciw et al. or Wardley et al. because Chavez et al. teaches the well known use of lyophilization to preserve and store FIV vaccine compositions in containers and the use of a sterile diluent (in a second container) to rehydrate the vaccine composition. It would have been obvious for the ordinary skilled artisan to do this because of the known benefit of lyophilization in storage and preservation of FIV vaccine compositions as taught by Chavez et al. Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim Objections

Claims 3, 4, 6, 15 and 23 are objected to because of the following informalities: Claims 3, 4, 6, 15 and 23 recite the abbreviations MA, CA NC, SU, TM, PR, RT, DU and IN without first indicating what these abbreviations denote. It is noted that the

abbreviations GAG, POL, ENV, Rev and Vif recited in the claims are so well known in the retroviral (or lentiviral) art as to need no further definition. Appropriate correction is required.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID GUZO
PRIMARY EXAMINER

David Guzo
January 6, 2006